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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,970	01/18/2001	Edmund Bauerlein	0107-018A	8968

7590 08/26/2003

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EXAMINER
GIBBS, TERRA C

ART UNIT	PAPER NUMBER
1635	7

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/764,970	BAUERLEIN ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17, 18, and 19* is/are pending in the application.

4a) Of the above claim(s) *18 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 17, 18, and 19 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 17, drawn to a magnetosome having a surface, and comprising a magnetite monocrystal having a diameter of at least 45 nm surrounded by a phospholipid membrane, and at least one therapeutic agent, classifiable in class 424, subclass 9.3.

II. Claim 18, drawn to a process of treating a tumoral disease, inflammatory process, or metabolic disease, comprising the administration of a magnetosome having a surface, and comprising a magnetite monocrystal having a diameter of at least 45 nm surrounded by a phospholipid membrane, and at least one therapeutic agent, classifiable in class 514, subclass 2.

III. Claim 19, drawn to a process for removing diseased cells, comprising the administration of a magnetosome having a surface, and comprising a magnetite monocrystal having a diameter of at least 45 nm surrounded by a phospholipid membrane, and at least one therapeutic agent, classifiable in class 435, subclass 69.1.

The inventions are distinct, each from the other because of the following reasons:

The composition invention of Group I is related to the method inventions of Groups II and III as product and process of use. The inventions can be shown to be distinct if either or

both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products can be used in materially different processes of use. For example, the magnetosome having a surface, and comprising a magnetite monocrystal having a diameter of at least 45 nm surrounded by a phospholipid membrane, and at least one therapeutic agent of Group I can be used as a diagnostic agent for tumoral diseases, which is a materially different process than a method of treating a disease or a method of removing disease cells as in Groups II and III.

Inventions of Groups II and III are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are drawn to a method of treating a disease (Group I) and a method for removing diseased cells (Group II). In the instant case the different inventions are not disclosed as capable of use together and have different operations, functions, and effects. The two methods have different and noninterchangable steps that lead to different ends (e.g. methods of treatment vs. method of removing diseased cells). The methods of Group I can be used for therapeutic purposes while the methods of Group II can be used for diagnostic purging. The differences between Groups II and III are further underscored by their different classifications and independent search status. Thus, they are unrelated and patentably distinct from each other.

Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

During a telephone conversation with Attorney William Hwang on or around July 16, 2003, a provisional election was made with traverse to prosecute the invention of Group I, claim 17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 18 and 19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Claim 17 is examined on the merits.

Priority

The reference to priority in the first line of the Specification should be updated with current serial numbers where patents have issued. Appropriate correction is required.

The instant application claims priority to USSN 09/397,705, filed 09/01/99, as a divisional. However, the instant application claims an invention not presented in the parent

application (09/397,705) and further, appears to have a different disclosure than that of the parent application. For example, in comparing the Specification of the instant application with the Specification of the parent application, Table 2 of the instant application appears to be missing data that is present in the parent application (see Table 2, 110 h time point). Additionally, the instant application claims a magnetosome having a surface, and comprising a magnetite monocrystal having a diameter of at least 45 nm surrounded by a phospholipid membrane, and at least one therapeutic agent (see claim 17). The limitation of at least 45 nm is not found in the parent application. Accordingly, the instantly claimed invention has not been given priority back to the filing date of the parent application.

Specification

The Specification is objected to because there is no Abstract. It is noted that Applicant provided an Abstract in the Amendment filed May 7, 2001 in Paper No. 5, however the Amendment was not entered because the Amendment was not submitted on a separate sheet of paper as required by amendment practice. See MPEP § 608.01(b). Correction is required.

Applicant is further reminded of the proper language and format for an abstract of the disclosure: The Abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the Abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "**said**," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "**aforesaid**".

Further, Applicant should note, if the Abstract filed, May 7, 2001 is resubmitted in proper format, it may be entered, however, it may raise an issue under new matter (see 35 U.S.C. 112, first paragraph rejection against claim 17 as failing to comply with the written description requirement below).

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 17 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,251,365 ('365). Although the conflicting claims are not identical, they are not patentably distinct from each other because the magnetosome having a surface, and comprising a magnetite monocrystal having a maximum diameter of 45 nm surrounded by a phospholipid membrane of claim 1 of ('365) overlaps in scope with the magnetosome having a surface, and comprising a magnetite monocrystal having a diameter of at least 45 nm surrounded by a phospholipid membrane of the instant invention. The magnetosome having a diameter of at least 45 nm of the instant invention is an obvious species of the magnetosome having a maximum diameter of 45 nm of ('365). Therefore, a magnetosome having a diameter of exactly 45 nm of the patent would claim the same inventive concept of a magnetosome having a diameter of exactly 45 nm of the instant invention. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or an amendment to the claims to exclude a magnetosome having a diameter of exactly 45 nm may be used to overcome this rejection.

Claim Rejections - 35 USC § 112

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described

in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 17 is drawn to a magnetosome having a surface, and comprising a magnetite monocrystal having a diameter of "at least 45 nm" surrounded by a phospholipid membrane, and at least one therapeutic agent. There is no literal or inherent support in the instant Specification as filed for a magnetosome having a surface, and comprising a magnetite monocrystal having a diameter of at least 45 nm. Additionally, the parent application for which the instant application claims benefit contains no specific or inherent support for a magnetosome having a surface, and comprising a magnetite monocrystal having a diameter of "at least 45 nm" surrounded by a phospholipid membrane, and at least one therapeutic agent.

The specification, at page 1, lines 1-2, recites "The invention relates to specific magnetosomes with magnetic particles of maximally 43-45 nm". However, the Specification does not have support for "a magnetosome having a surface, and comprising a magnetite monocrystal having a diameter of at least 45 nm surrounded by a phospholipid membrane, and at least one therapeutic agent". Therefore, the limitation "at least 45 nm" (e.g. anything greater than 45 nm) is a new matter issue.

Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP § 2163.06 which states, when filing an amendment, an applicant should show support in the original disclosure for new or amended claims (See MPEP § 714.02 and § 2163.06).

It is noted that the Abstract filed, May 7, 2001 includes the limitation of "at least 45 nm", however, this Abstract was submitted post filing of the instant application and does not provide support at the date of filing of the instant application (01/18/01).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Matsunaga et al. (Reprints from Ferrites: Proceedings of the Sixth International Conference on Ferrites, 1992).

Claim 17 is drawn to a magnetosome having a surface, and comprising a magnetite monocrystal having a diameter of at least 45 nm surrounded by a phospholipid membrane, and at least one therapeutic agent.

Matsunaga et al. disclose magnetic bacteria, AMB-1, containing magnetosomes, with an average particle size of 50-100 nm in diameter, covered with thin lipid films and immobilized enzymes, antibodies, or nucleic acids, can be utilized in biosensing systems with increased sensitivity (see page 262, first paragraph).

Therefore, Matsunaga et al. anticipate claim 17.

Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Matsunaga et al. [U.S. Patent No. 6,033,878] ('878) as evidenced by Matsunaga et al. (Reprints from Ferrites: Proceedings of the Sixth International Conference on Ferrites, 1992).

Matsunaga et al. ('878) disclose isolated magnetic bacteria, AMB-1, which synthesized magnetic particles of magnetite of a very small size, which were enveloped by a membrane of phospholipids with chemically bound enzymes or antibodies (see Abstract, column 4, lines 4-16 and column 5, lines 12-24).

Matsunaga et al. ('878) do not explicitly state the diameter size of AMB-1, however AMB-1 has an average particle diameter of between 50 and 100 nm as evidenced by Matsunaga et al. (Reprints from Ferrites: Proceedings of the Sixth International Conference on Ferrites, 1992), see Introduction, for example. An average particle diameter of between 50 and 100 would be inherent to the AMB-1 of '878. This inherency is further evidenced by Applicants arguments filed in the parent application USSN 09/397,705, in Paper No. 13, filed October 16, 2000, where Applicants cited Matsunaga et al. (Reprints from Ferrites: Proceedings of the Sixth International Conference on Ferrites, 1992) as disclosing the size of AMB-1 particles by stating: "specifically identifies average particle diameters of magnetic particles AMB-1 and MGT-1 used by Matsunaga, specified as being between 50 and 100 nm, with the largest representing the mature crystal" (see forth paragraph, for example).

Therefore, Matsunaga et al. ('878) anticipate claim 17.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (703) 306-3221. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-8693 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

tcg August 19, 2003

KAREN LACOURCIERE
PATENT EXAMINER